

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

O P E U C
OCT 24 2003
U. S. PATENT & TRADEMARK OFFICE
Applicant: Buechler et al.Title: MARKERS FOR DIFFERENTIAL
DIAGNOSIS AND METHODS OF
USE THEREOF

Appl. No.: 10/603,891

Filing Date: 06/24/2003

Examiner: Unknown

Art Unit:

CERTIFICATE OF MAILING

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10/21/03

(Date of Deposit)

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

Applicants submit herewith on Form PTO/SB/08 a listing of the documents cited by or submitted to the U.S. PTO in parent application Serial No. 10/330,696, filed 12/27/2002. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

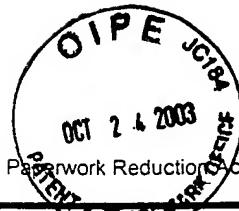
Respectfully submitted,

Date 10/21/03

By Barry Wilson

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Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	10/330,696
Date Submitted: <u>April 14, 2003</u>		Filing Date	12/23/2002
(use as many sheets as necessary)		First Named Inventor	Kenneth F. Buechler
Sheet	1	of	27
		Attorney Docket Number	071949-5602

U.S. PATENT DOCUMENTS

Examiner Signature		Date Considered	
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OCT 24 2003

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				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	071949-5602

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	B1	EPO	999447A1					
	B2	WO	01/16599 A1					

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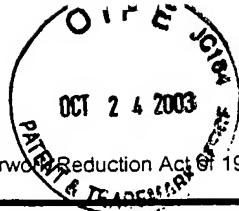
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	C1	Aggarwal et al., "Evaluation of serum lipid profile and cardiac enzyme changes in cerebrovascular accidents," <i>JIMA</i> , 93:331-332 (1995).	
	C2	Akiyama et al., "Changes in serum concentrations of matrix metalloproteins, tissue inhibitors of metallo proteinases and Type IV collagen in patients with various types of glomerulonephritis," <i>Res. Commun. In Mol. Path. and Pharm.</i> , 95(2): 115-128 (1997).	
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	C6	Asano, Y. et al., "Clinical Significance of surfactant protein D as a serum marker of evaluating pulmonary fibrosis in patients with systemic sclerosis," <i>Arthritis Rheum</i> 44(6):1363-9 (June 2001).	
	C7	Austgulen et al., "Increased maternal plasma levels of soluble adhesion molecules (ICAM-1, VCAM-1, E-selectin) in preeclampsia," <i>Eur. J. Obstet. Gynecol. Reprod. Biol.</i> , 71:53-58 (1997).	
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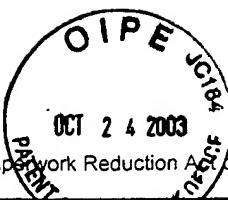
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	C10	Balagopalakrishna, C. et al., "Modification of low density lipoproteins by erythrocytes and hemoglobin under hypoxic conditions, <i>Adv. Exp. Med. Biol.</i> 411:337-345 (1997).	
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SB-1449B-08 (Rev. 1-2002) Form 1449B/PTO

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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

Date Submitted: April 14, 2003

(use as many sheets as necessary)

Sheet 4 of 27

Application Number	10/330,696
Filing Date	12/23/2002
First Named Inventor	Kenneth F. Buechler
Group Art Unit	Unassigned
Examiner Name	Unassigned

Attorney Docket Number 071949-5602

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
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	C26	Blann, A.D. et al., "Evidence of platelet activation in hypertension," <i>Thromb. Haemost.</i> 77:1077-1080 (1997).	
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	C29	Bollensen et al., "Adenylate kinase enzyme activity in cases of brain infarction," <i>Acta Neurol. Scand.</i> 79:53-58 (1989).	
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	C36	Brown, D.L. et al., "Identification of 92-kd gelatinase in human coronary atherosclerotic lesions," <i>Circulation</i> 91:2125-2131 (1995).	

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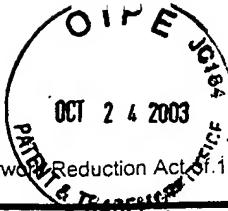
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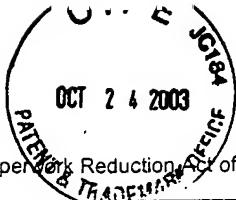
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	C37	Caligiuri et al., "Immune system activation follows inflammation in unstable angina: pathogenetic implications," <i>J.Am. Coll. Cardiol.</i> 32:1295-1304 (1998).	
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	C41	Carter et al., "Purification, cloning, expression and biological characterization of an interleukin-1 receptor antagonist protein," <i>Nature</i> 344:633-638 (1990).	
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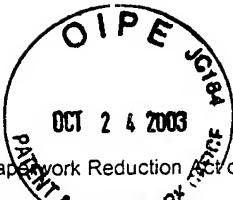
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	C51	Dao et al., "Utility of B-Type Natriuretic Peptide in the Diagnosis of Congestive Heart Failure in an Urgent-Care Setting," <i>J. Am. Coll. Cardiol.</i> 37:379-85 (2001).	
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	C56	De Rose et al., "Circulating adhesion molecules in cystic fibrosis," <i>Am. J. Respir. Crit. Care Med.</i> 157: 1234-1239 (1998).	
	C57	Depre, C. et al., "Expression of inducible nitric oxide synthase in human coronary atherosclerotic plaque," <i>Cardiovasc. Res.</i> 41:465-472 (1999).	
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	C59	Dinerman, J.L. et al., "Increased neutrophil elastase release in unstable angina pectoris and acute myocardial infarction," <i>J. Am. Coll. Cardiol.</i> 15:1559-1563 (1990).	
	C60	Doubell, A.F. et al., "Identification and immunolocalisation of annexins V and VI, the major cardiac annexins, in rat heart," <i>Cardiovasc. Res.</i> 27:1359-1367 (1993).	
	C61	Dunlop, L.C. et al., "Characterization of GMP-140 (P-selectin) as a circulating plasma protein," <i>J. Exp. Med.</i> 175:1147-1150 (1992).	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/330,696
Date Submitted: April 14, 2003 (use as many sheets as necessary)				Filing Date	12/23/2002
Sheet	7	of	27	First Named Inventor	Kenneth F. Buechler
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	071949-5602

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
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	C65	Emsley et al., "Crystal structure of the von Willebrand factor A1 domain and implications for the binding of platelet glycoprotein Ib," <i>Journal of Biological Chemistry</i> 273(17): 10396-10401, (1998).	
	C66	Endo et al., "Elevated levels of serum and plasma metalloproteinases in patients with gastric center," <i>Anticancer Research</i> 17:2253-2258 (1997).	
	C67	Endo, S. et al., "Plasma interleukin 8 and polymorphonuclear leukocyte elastase concentrations in patients with septic shock," <i>J. Inflamm.</i> 45:136-142 (1995).	
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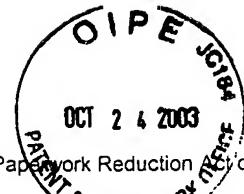
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	C77	Forssmann et al., "The endocrine heart and natriuretic peptides: histochemistry, cell biology, and functional aspects of the renal urodilatin system," <i>Histochem Cell Biol</i> 110: 335-357 (1998).	
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Sheet 10 of 27

Application Number 10/330,696

Filing Date 12/23/2002

First Named Inventor Kenneth F. Buechler

Group Art Unit Unassigned

Examiner Name Unassigned

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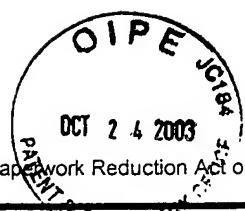
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/330,696
Date Submitted: April 14, 2003 (use as many sheets as necessary)				Filing Date	12/23/2002
Sheet	13	of	27	First Named Inventor	Kenneth F. Buechler
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	071949-5602

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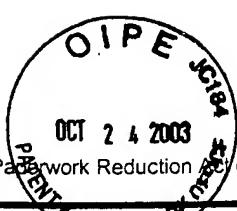
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	C143	Kato, K. et al., "Immunoassay of human muscle enolase subunit in serum: a novel marker antigen for muscle diseases," <i>Clin. Chim. Acta</i> 131:75-85 (1983).	
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				Attorney Docket Number	071949-5602

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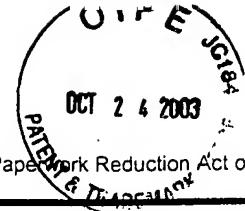
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Date Submitted: April 14, 2003 (use as many sheets as necessary)				Filing Date	12/23/2002
				First Named Inventor	Kenneth F. Buechler
				Group Art Unit	Unassigned
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Sheet	15	of	27	Attorney Docket Number	071949-5602

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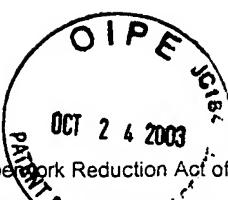
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	C182	Livrea, M.A. et al., "Oxidative modification of low-density lipoprotein and atherogenetic risk in β-thalassemia," <i>Blood</i> 92:3936-3942 (1998).	
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Date Submitted: April 14, 2003

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Sheet 19 of 27

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Application Number	10/330,696
Filing Date	12/23/2002
First Named Inventor	Kenneth F. Buechler
Group Art Unit	Unassigned
Examiner Name	Unassigned

Attorney Docket Number 071949-5602

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	C222	Nishizawa et al., "Protein kinase C δ and α are involved in the development of vasospasm after subarachnoid hemorrhage," <i>Eur. J. Pharmacol.</i> 398: 113-119 (2000).	
	C223	Nomura, M. et al., "Serum β -enolase in acute myocardial infarction," <i>Br. Heart J.</i> 58:29-33 (1987).	
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	C227	Ogawa, H. et al., "Plasma platelet-derived growth factor levels in coronary circulation in unstable angina pectoris," <i>Am. J. Cardiol.</i> 69:453-456 (1992).	
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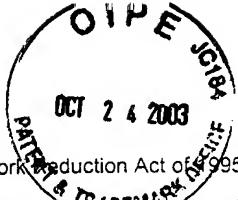
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/330,696
Date Submitted: April 14, 2003 (use as many sheets as necessary)				Filing Date	12/23/2002
				First Named Inventor	Kenneth F. Buechler
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
Sheet	20	of	27	Attorney Docket Number	071949-5602

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
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	C236	Peter, K. et al., "Circulating vascular cell adhesion molecule-1 correlates with the extent of human atherosclerosis in contrast to circulating intercellular adhesion molecule-1, E-selectin, P-selectin, and thrombomodulin," <i>Arterioscler. Thromb. Vasc. Biol.</i> 17:505-512 (1997).		
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	C249	Romanic et al., "Matrix metalloproteinase expression increases after cerebral focal ischemia in rats," <i>Stroke</i> 29:1020-1030 (1998).	
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				Group Art Unit	Unassigned
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	C263	Schins and Borm, "Epidermological evaluation or release of monocyte TNF- α as an exposure and effect marker in pneumonoconiosis: a five year follow up study of coal workers," <i>Occup. Environ. Med.</i> 52:441-50 (1995).	
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	C270	Shibata, M. et al., "Effect of magnesium sulfate pretreatment and significance of matrix metalloproteinase-1 and interleukin-6 Levels in coronary reperfusion therapy for patients with acute myocardial infarction," <i>Angiology</i> 50:573-582 (1999).	
	C271	Shimomura, H. et al., "Serial changes in plasma levels of soluble P-selectin in patients with acute myocardial infarction," <i>Am. J. Cardiol.</i> 81:397-400 (1998).	
	C272	Shyu et al., "Serum levels of intercellular adhesion molecule-1 and E-selectin in patients with acute ischaemic stroke," <i>J. Neurol.</i> 244:90-93 (1997).	
	C273	Siess, W., "Lysophosphatidic acid mediates the rapid activation of platelets and endothelial cells by mildly oxidized low density lipoprotein and accumulates in human atherosclerotic lesions," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 96, 6931-6936 (1999).	
	C274	Sixma et al., "Von Willebrand factor and the blood vessel wall," <i>Mayo Clin. Proc.</i> 66:628-633 (1991).	

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	C275	Skogseid et al., "Increased serum creatine kinase BB and neuron specific enolase following head injury indicates brain damage," <i>Acta Neurochir (Wein)</i> , 115: 106-111 (1992).	
	C276	Sobel, M. et al., "Circulating platelet products in unstable angina pectoris," <i>Circulation</i> 63:300-306 (1981).	
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	C282	Squadrito, F. et al., "Thrombolytic therapy with urokinase reduces increased circulating endothelial adhesion molecules in acute myocardial infarction," <i>Inflamm. Res.</i> 45:14-19 (1996).	
	C283	Steiner et al., "Increased levels of soluble adhesion molecules in Type 2 (Non-insulin dependent) diabetes mellitus are independent of glycaemic control," <i>Thromb. Haemost.</i> 72:979-984 (1994).	
	C284	Stockman et al., "Secondary structure and topology of interleukin-1 receptor antagonist protein determined by heteronuclear three-dimensional NMR spectroscopy," <i>Biochemistry</i> 31:5237-5245 (1992).	
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	C286	Suga et al., "Clinical significance of MCP-1 levels in BALF and serum in patients with interstitial lung diseases," <i>Eur. Respir. J.</i> 14:376-382 (1999).	

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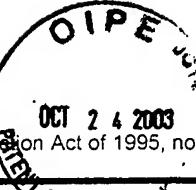
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Sheet 24 of 27

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First Named Inventor	Kenneth F. Buechler
Group Art Unit	Unassigned
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	C287	Switalska et al., "Radioimmunoassay of human platelet thrombospondin: different patterns of thrombospondin and β -thromboglobulin antigen secretion and clearance from the circulation," <i>J. Lab. Clin. Med.</i> 106: 690-700 (1985).	
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Date Submitted: <u>April 14, 2003</u> (use as many sheets as necessary)				Application Number	10/330,696
Sheet	25	of	27	Filing Date	12/23/2002
				First Named Inventor	Kenneth F. Buechler
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	071949-5602

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	C300	Tohgi et al., "Coagulation-fibrinolysis abnormalities in acute and chronic phases of cerebral thrombosis and embolism," <i>Stroke</i> 21: 1663-1667 (1990).	
	C301	Tomoda, H. and Aoki, N., "Plasma soluble P-selectin in acute myocardial infarction: effects of coronary recanalization therapy," <i>Angiology</i> 49:807-813 (1998).	
	C302	Tousoulis et al., "Von Willebrand factor in patients evolving Q-wave versus non-Q-wave acute myocardial infarction," <i>Int. J. Cardiol.</i> 56:259-262 (1996).	
	C303	Trotter et al., "Immunoreactive myelin proteolipid protein-like activity in cerebrospinal fluid and serum of neurologically impaired patients," <i>Ann. Neurol.</i> , 14: 554-558 (1983).	
	C304	Tsui, R. et al., "Human heart-type cytoplasmic fatty acid-binding protein in serum and urine during hyperacute myocardial infarction," <i>Int. J. Cardiol.</i> 41:209-217 (1993).	
	C305	Uchiyama et al., "Alterations of platelet, coagulation, and fibrinolysis markers in patients with acute ischemic stroke," <i>Semin. Thromb. Hemost.</i> 23: 535-541 (1997).	
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	C307	Usui, A. et al., "β-Enolase in blood plasma during open heart surgery," <i>Cardiovasc. Res.</i> 23:737-740 (1989).	
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	C313	Veerkamp, J.H. and Maatman, R.G., "Cytoplasmic fatty acid-binding proteins: their structure and genes," <i>Prog. Lipid Res.</i> 34:17-52 (1995).	

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Date Submitted: April 14, 2003 (use as many sheets as necessary)				Filing Date	12/23/2002
Sheet	26	of	27	First Named Inventor	Kenneth F. Buechler
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	071949-5602

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	C314	Venge, "Surrogate markers for monitoring inflammation in asthma," <i>Clinical and experimental allergy</i> , 23 (2):3-7 (1993).	
	C315	Viera et al., "Isolation and expression of human cytokine synthesis inhibitory factor cDNA clones: homologyto Epstein-Barr virus open reading frame BCRFI," <i>Proc. Natl. Acad Sci. USA</i> 88:1172-76 (1991).	
	C316	Virchow et al., "Sputum ECP levels correlate with parameters of airflow obstruction," <i>Am. Rev. Respir. Dis.</i> 146:604-6 (1992).	
	C317	Wallace, J.M. et al., "The assessment of platelet derived growth factor concentration in post myocardial infarction and stable angina patients," <i>Ann. Clin. Biochem.</i> 35:236-241 (1998).	
	C318	Ward et al., "Binding activities of a repertoireof singleimmunoglobulin variable domains secreted from <i>Escherichia coli</i> , <i>Nature</i> 341:544-546 (1989).	
	C319	Whicher et al., "Procalcitonin as an acute phase marker," <i>Ann. Clin. Biochem.</i> 38: 483-93 (2001).	
	C320	Wilkins et al., "The natriuretic-peptide family," <i>Lancet</i> , 349:1307-1310 (1997).	
	C321	Wilson et al., "Simplified conjugation chemistry for coupling peptides to F(ab') fragments: autologous red cell agglutination assay for HIV-1 antibodies," <i>J. Immunol. Methods</i> 175:267-273 (1994).	
	C322	Winnikes et al., "Head activator as a potential serum marker for brain tumor analysis," <i>Eur. J. Cancer</i> 28:421-424 (1992).	
	C323	Woertgen et al., "Comparison of serial S-100 and NSE serum measurements after severe head injury," <i>Acta Neurochir (Wien)</i> 139: 1161-1165 (1997).	
	C324	Xu, Y. et al., "Lysophosphatidic Acid as a potential biomarker for ovarian and other gynecologic cancers," <i>JAMA</i> 280:719-723 (1998).	
	C325	Yamane et al., "Serum levels of KL-6 as a useful marker for evaluating pulmonary fibrosis in patients with systemic sclerosis," <i>J. Rheumatol.</i> 27:930-4 (2000).	
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	C327	Yap et al., "Contraction to big endothelin-1, big endothelin-2 and big endothelin-3, and endothelin-converting enzyme inhibition in human isolated bronchi," <i>Br. J. Pharmacol.</i> 129:170-7 (2000).		
	C328	Yarmush et al., "Coupling of antibody-binding fragments to solid-phase supports: site-directed binding of F(ab') ₂ fragments," <i>J. Biochem. Biophys. Methods</i> 25:85-97 (1992).		
	C329	Yazdani, S. et al., "Percutaneous interventions alter the hemostatic profile of patients with unstable versus stable angina," <i>J Am Coll Cardiol</i> 30:1284-1287 (1997).		
	C330	Yoneda et al., "Identification of a novel adenylyl kinase system in the brain: Cloning of the fourth adenylyl kinase," <i>Mol. Brain Res.</i> 62:187-195 (1998).		
	C331	Yoshimoto, K. et al., "Human heart-type cytoplasmic fatty acid-binding protein as an indicator of acute myocardial infarction," <i>Heart Vessels</i> 10:304-309 (1995).		
	C332	Yoshimura et al., "Human monocyte chemoattractant protein-1 (MCP-1)," <i>FEBS Lett.</i> 244:487-493 (1989).		
	C333	Yoshitomi et al., "Plasma levels of adrenomedullin in patients with acute myocardial infarction," <i>Clin. Sci.</i> 94:135-9 (1998).		
	C334	Yukioka et al., "Plasma procalcitonin in sepsis and organ failure," <i>Ann. Acad. Med. Singapore</i> 30:528-31 (2001).		
	C335	Zucker et al., "Increased serum stromelysin-1 levels in systemic lupus erythematosus: lack of correlation with disease activity," <i>J. Rheumatol.</i> 26:78-80 (1999).		

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